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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/531,113
Filing Date: March 22, 2000
Appellant(s): BYRUM ET AL.

Thomas E. Holsten
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 31, 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject matter

The summary of the claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection t be reviewed on appeal in the brief is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Prior art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

Claims 1, 8-13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed subject matter is not supported by a specific; substantial or a well established utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use.

The claimed invention is drawn to a substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 5981 or a substantially purified nucleic acid molecule comprising a sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof. As noted earlier, a well-established utility is defined as a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of the a material, alone or taken with the knowledge of one skilled in the art. The specification discloses a number of general utilities for the nucleic acid molecule disclosed herein. For example, the specification discloses that the nucleic acid molecules may be used as molecule tags to isolate genetic regions, isolate genes, map genes and

determine gene function (page 15), in marker-assisted breeding programs (page 16), as antibodies (page 16), as primer and probes for the isolation of full length cDNAs or genes (page 28), in mutation detection (page 37), in the identification of polymorphism (page 38), as molecular markers (page 50), genetic mapping studies (page 49), in DNA-protein interaction (page 52) in methods of identifying chromosomes with translocation (page 52), in method of protein-protein interaction (page 60), in microarray based methods (page 54), in site directed mutagenesis (page 56) and in methods of transformation (page 61). None of theses asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequence being claimed. Likewise no direct connection is made between the claimed sequence or any of the numerous utilities claimed. The examples beginning at page 85 do not provide any disclosure which demonstrates the functionality of the claimed nucleic acid sequence or fragments thereof or complement thereof as for example, probes and/or primers to detect a mutation or as marker to determine gene function. Thus, further research is required to determine the specific utility of the claimed nucleic acid sequence.

Further, the claimed nucleic acid and/or the encoded protein are not supported by a substantially utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not

supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by Applicant to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the claimed use of the nucleic acid in the instant specification is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic molecules. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid or the encoded protein such that another non-asserted utility would be well established for the compounds.

Claim Rejections - 35 USC § 112

Claims 1 and 8-16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention based on the lack of utility as discussed above.

(10) Response to Argument

Appellant's arguments drawn to the above rejection have been fully reviewed and considered. However, they are not found persuasive for the reasons that follow. The paragraph numbers used in the response to argument section follow those used in the Brief.

7-A. - Appellant summarizes a portion of *Brenner v. Manson* which includes the allegation that Applicant has met their part of the bargain in that the claimed nucleic acid molecules supply the benefit to the public of the ability to identify the presence or absence of a polymorphism in a population of soybean plants. Applicant alleges that this benefit is specific, not vague or unknown and it is a "real world" or substantial benefit. Applicant further alleges that because the claimed nucleic acid molecules provide at least these benefits, this satisfy the utility requirement of 35 USC 101. Applicant alleges that because the specification teaches how to make and use the claimed nucleic acid molecules for the disclosed utilities, the enablement requirement of 35 USC 112 has been met.

In response, it is noted that the specification at pages 38-46 provides a general definition of what constitutes a polymorphism and general means for detecting or determining the existence of polymorphisms as known in the art. However, no disclosure or any polymorphisms is provide that is specific to the nucleic acid molecule (SEQ ID NO: 5981) recited in the claims 1 and 8-13. To the contrary, according to appellant's specification (e.g., page 45, 7-9), "one or more of the 48, 629 nucleic acids of the present invention, maybe utilized as markers or probes to detect polymorphisms...". The specification does not explain why any of the these nucleic acid molecules disclosed in the specification, or more specifically a nucleic acid molecule comprising the sequence of SEQ ID NO: 5981 would in fact be useful in detecting a polymorphism or

whether the claimed nucleic acid molecule can, in fact, be used to detect any polymorphism, whatsoever. The specification generally teaches using the claimed nucleic acid molecules to identify a polymorphism, but fails to teach that a polymorphism could in fact be detect, or a specific polymorphism could be detected.

Further, the specification provides no information with regards to the genes represented by the nucleic acid, and accordingly, detecting of the presence or absence of a polymorphism provides the barest information in regards to genetic heritage or association to a disease or condition. There are myriad of polymorphisms that are known to occur in nucleic acid molecules in plants, etc, both of the silent type and those that result in significant phenotypic effects. However, without, evidence characterizing those polymorphisms or information concerning the gene(s) represented by the claimed nucleic acid molecule(s) which may or may not comprises the polymorphisms or some type of association of the polymorphism with a genetic trait, disease or condition, nothing is gains and no substantial, specific or patentable utility is presented. Further research would be required to determine what said detection of polymorphism indicates and thus substantiates the Examiner's assertion that the claimed invention is not enabled due to lack of information provided in the specification and claims. This need for further research also supports the lack of currently available form of utility.

7-B. - Appellant summarizes the lack of utility rejection and alleges that the analysis made by the Examiner misstates the nature of the asserted uses, ignores disclosed utilities and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson.* Appellant states that the invention need only provide one identifiable benefit to satisfy 35 USC 101. In response, the Examiner maintains that Applicant has *not provided a single identifiable benefit* that satisfy

35 USC 101 because the alleged utilities recited in the specification are general utilities and are not considered to be specific or substantial in view of the limited information provided in the specification. No plant traits are attributed to any SEQ ID NO:, no complete gene sequence is discussed for any SEQ ID NO, especially the claimed sequence of SEQ ID NO: 5981. No DNA maps or chromosomal locations are identified, no polymorphism is identified and the specification does not disclose how a polymorphism would be recognized by those of ordinary skill in the art given the incomplete sequences disclosed. The specification only provides general uses of the claimed nucleic acid molecules with no evidence or factual experimentation to substantiate those uses. These arguments are an allegation without arguing the specifics of the rejection and are thus non-persuasive.

Appellant summarizes a test for utility directed to an "identifiable benefit". Applicant argues that identifiable benefits are provided in the specification, for example, use to identify the presence or absence or a polymorphism, and use as a hybridization probe for expression profiling. Appellant asserts that either of these utilities described alone is enough to satisfy section 101.

In response, the Examiner maintains that none of these uses, e.g., to identify the presence or absence of polymorphism, and use as a hybridization probe for expression profiling, is specific to any of the 48,629 sequences recited in the instant application. The utilities are merely generic in nature. The specification has not established if the claimed nucleic acid molecule or any of other sequences recited in the application is a coding nucleic acid (thus expressed, and could be detected in an expression assay) or a regulatory element. All discussion of polymorphisms in the specification is generic in nature and no evidence is provided or any

polymorphisms identified which establishes that polymorphisms for the claimed nucleic acid molecules in fact exist. The specification lacks disclosure of any specific or substantial phenotypic association or even predisposition regarding any claimed nucleic acid. This lack of such association can only be remedied, if such association with any phenotype even exists for the claimed nucleic acids, by further research. The specification teaches a marker utility for the instant invention and procedures for marker usage which includes expression profiling but again this discussion is generic in nature without any association or even vague connection to any of the sequences recited in the specification or claimed in claims 1 and 8-13. Thus, these generic procedural guidelines lack specificity as well as substantiality regarding the utility of the instantly claimed invention, which is directed to a particular nucleic acid molecule. Applicant's arguments are non-persuasive.

7-B(1) and 7-B(1)(a). - Applicant in this section again summarizes the Examiner's rejection and argues in part (a) that that one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Applicant points to pages 38-45 of the specification. Applicant argues that the disclosed utilities are directly analogous to the utilities of a microscope to locate and measure nucleic acids within a sample, cell, or organism and also indicates a comparison to gas chromographs, etc.

In response, while it is acknowledged that a microscope and gas chromograph have well established utilities where known analyses are available with a clearly useful result. The use of the tools may not be beneficial if the practitioner has no idea what it is intended to look for. Appellant relies on the detection of the presence or absence of a polymorphism when no polymorphism or lack of any polymorphism has indeed been established. No comparable well-

known use have been set forth or is known for the instantly claimed invention. No already determined analysis results are known for the instantly claimed invention. Thus utilizing tools such as a microscope or gas chromograph may be compared to a "fishing experiment" to see what information can be obtained without knowing what the information means or corresponds to. The microscope, etc., is not analogous to the instant invention as there is no well-known use(s) for the instant invention other than for further research to find a utility.

Appellant then argues that the absence of a polymorphism demonstrates a common genetic heritage between two populations. In response, no polymorphism is disclosed for the instant application. No genetic heritage or common heritage have been investigated or established by the instant disclosure and no factual support has been presented that suggest that the absence of a polymorphism demonstrates a common genetic heritage. In fact, no association studies whatsoever have been presented in the instant disclosure or even one polymorphism that can be detected with the claimed nucleic acid molecule. The specification fails to show any specific correspondence between the disclosed general utility and the claimed subject matter, regardless of any specific application requiring detection of polymorphism. Using the invention to first determine whether or not the claimed nucleic acid molecule can, in fact, detect a polymorphism is to determine whether or not the claimed invention has a utility that requires detecting a polymorphism, i.e., it is 'use testing' and not substantial. Therefore, the Examiner asserts that Applicant's arguments are not persuasive to support a specific, asserted or substantial utility.

7.-B(1)(b) - Appellant argues that the asserted utility of a probe or primer source is substantial because the specification discloses that the claimed nucleic acid can be used to isolate nucleic

acid from variety of other plant species. In response, the Examiner asserts that this argument is not persuasive. While it may be true that the nucleic acid is capable of isolating other nucleic acids from plants and how substantial such use of the nucleic acid molecules would have is yet to be determined. Again, as noted earlier, the present specification does not attribute any property in terms of plant trait, or phenotype to the nucleic acid molecule as set forth in the claims 1 and 8-13. In the absence of such information, using the claimed nucleic acid molecules, which themselves lack substantial utility, does not represent a substantial utility. Appellant argues that the claimed nucleic acid may be useful in searching for promoters or may be used to initiate chromosome walking. In response, the specification fails to demonstrate that any of the 48,629 nucleic acid molecules, especially, SEQ ID NO: 5981 would be useful in obtaining a successful result from such as search. The specification does not provide any expectation of successfully using the disclosed nucleic acid molecules of the specification to isolate promoters of tissue enhance, tissue specific, cell-specific, cell-type, developmentally or environmentally regulate expression profiles. The specification fails to disclose any characteristics of the corresponding promoter, or any other promoter within "chromosome walking" distance, neither structural characteristics, by which the promoter might be identified, nor functional characteristics, by which a specific and substantial use for the promoter might be determined. A nucleotide sequence is identified during the chromosome walk as a putative promoter by sequence analysis, is then subcloned into operable linkage with a reporter gene and transfected into an appropriate cell, but found not to express the reporter gene in the cells. This result could mean the putative promoter: is not truly a promoter, i.e. a false positive; is not the corresponding promoter; or is incomplete, i.e. lacked additional sequence elements required for promoter activity in the seed

pod cells. Appellant did not identify any nucleic acid sequence during a chromosome walk. Appellant merely isolated the claimed nucleic acid molecule without further testing, evaluating or calibrating the claimed nucleic acid molecule for any particular use. Further research would be required to define a specific and/or substantial utility for the claimed nucleic acid molecules that supports this lack of utility rejection.

7-B(2) - Appellant summarizes some legal issues regarding "substantial" utility, and asserts that there can be no question that one skilled in the art can used the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphism (Brief, p. 10). However, it is once again reiterated that the specification does not identify even one specific or non-specific polymorphism that can be detected with the claimed nucleic acid molecule; the specification fails to show any specific correspondence between the disclosed general utility and the claimed subject matter, regardless of any specific application requiring detection of polymorphisms. Therefore, further experimentation would be required to reasonably confirm and practice this putative utility.

Appellant further argues that there is no question that the public has recognized the benefits provided by the claimed subject matter. However, Appellant has not provided any specific arguments with regard to the claimed subject matter, only general commentary about EST molecules. These arguments are not found persuasive a polymorphism is a collective concept defined by at least two variants or (alleles) found within members of a species collectively. Thus, one detects the presence of a polymorphism by analysing multiple members of the species, i.e. analyzing a population for any genetic associations. The specification fails to disclose a specific and substantial utility for the claimed invention in the capacity of detecting

polymorphisms, because it does not disclose whether the claimed nucleic acid molecules can, in fact, be used to detect any polymorphism or any other variant sequences whatsoever. The specification generally teaches using the claimed isolated nucleic acid to identify a polymorphism, but fails to teach that a polymorphism could in fact be detected, or a specific polymorphism that could be detected. The specification generally teaches using a polymorphism, detectable with the claimed nucleic acid molecules, as a molecular marker for a linked trait of interest, but fails to teach either the polymorphism or the trait of interest. Without knowing any further information in regard to the gene represented by an EST, as here detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage. Thus, further research is necessary to reasonably confirm and practice this putative utility.

Appellant further argues that a multi-million dollar industry has been established for ESTs which may also find utility as industrial products for fermentation process. In response, there is no instant support or evidence for the instant claimed nucleic acid molecules being of monetary value. No fermentation process or utility involving any type of fermentation is disclosed anywhere in the specification. Therefore to acquire utility based on a fermentative process, some type of specific and substantial fermentation usefulness would be required and discussed. No such specific or substantial utility have been asserted in the instant application and thus Appellant arguments are not persuasive to support utility for the claimed nucleic acid molecules.

Appellant argues that the market participants for EST products are primarily sophisticated corporation with highly knowledgeable scientist. In response, again no market value has been determined, discussed or described for the instantly claimed nucleic acid

molecules. Therefore, these allegations of such value are without factual support and are not persuasive. It is also pointed out that ESTs in such markets are valued in large sets of ESTs and not singly unless some specific and substantial utility for a particular EST is known. The instantly claimed nucleic acid molecules do not correspond to such large sets of ESTs as sold either in sequence information form or as combinatorial sets. Likewise, the ESTs of the instant invention do not correspond to a specific, known or particular nucleic acid sequence, which validates a specific or substantial use for the instant invention. While one may assume that the claimed nucleic acids, in combination with other nucleic acids, could be used to monitor changes in expression of the gene that encompasses the nucleic acid as depicted in, e.g., SEQ ID NO: 5981 (such as ESTs in microarray analysis). However, the specification provides no guidance that would allow a skilled artisan to use data relating to expression of such a gene in any practical way. The specification provides no guidance regarding what the SEQ ID NO: 5981-specific information derived from a gene expression experiment would mean. Hence, contrary to Appellant's assertion, further experimentation would be required to identify a "real world" use. One would be required to carry out further testing and screening to determine a "real world" use. A negative result to such a screen would tell what the nucleic acid is not and cannot be used for. A positive result to such a screen requires further experimentation to determine, what, if anything, such a change means. It is not an immediate benefit except in the sense to indicate that further research might yield a "real world use". To elaborate further, suppose that a research found that expression of the nucleic acid molecule set forth in the claim 1 and 8-013 was increased when a cell was treated with a particular agent. The specification provides no basis on which a skilled worker would be able to determine whether that result is meaningful or not.

Maybe the meaning in a change in expression would depend on other factors, but again the specification provides no hint as to what other factors might be important. For example, would it depend on what agent is used, what cell type is used, the behavior of other genes, and if so, which genes and what behavior is significant, or the degree of increase? The specification simply provides no guidance as to how to interpret the results that might be seen using the nucleic acid molecules of the claimed invention in a gene expression assay.

7.B(3) - Appellant argues that the credibility issues is generally directed to "hare-brained" utilities or wholly inoperative inventions. In response, the Examiner maintains that no specific, or substantial or well-established utility for the disclosed nucleic acid molecules of the instant invention has been asserted by Appellant or disclosed in the specification as discussed earlier. Since no specific, or substantial or well-established utility has been set forth for any nucleic acid molecules of the instant invention, especially the claimed nucleic acid sequence of SEQ ID NO: 5981, no credibility has been ascertained. The examiner maintains that the disclosure in this case does not provide a specific benefit in currently available form and therefore lacks the substantial utility required by 35 USC 101. Appellant's arguments are not found persuasive.

7C. - Appellant asserts that the enablement of the claimed nucleic acid molecules has been challenged. Appellant argues that the rejection is erroneous and has been overcome by the arguments states above regarding the utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention". In response, it is noted that the enablement rejection is based on the fact that no patentable utility has been set forth for the claimed invention and thus, one would not know how to use the claimed invention based on the disclosure of the specification. This rejection is

simply a corollary of the finding of lack of utility as discussed above. All of the arguments set forth by the Examiner for a lack of utility are applied here for lack of enablement. The Examiner again asserts that since no specific, substantial or well-established utility has been set forth by Appellant, one would skilled in the art would not know how to make or use the invention. Accordingly, Appellant's arguments are not persuasive.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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